

PATENT  
Customer No. 22,852  
Attorney Docket No. 02481.1702

1617  
\$

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Bernward SCHÖLKENS et al.

Application No.: 09/645,556

Filed: August 25, 2000

For: PHARMACEUTICAL  
FORMULATIONS AND USE  
THEREOF IN THE PREVENTION OF  
STROKE, DIABETES AND/OR  
CONGESTIVE HEART FAILURE

)  
)  
) Group Art Unit: 1617  
)  
) Examiner: J. Kim  
)  
) Confirmation No.: 3278  
)  
)  
)  
)  
)  
)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents on the attached listing. This Supplemental Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed foreign and non-patent literature documents are attached. Copies of the U.S. patent publications are not enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

The following applies to the non-English language documents:

EP 0 317 878: This document contains English language claims on pages 17-19. This document is also believed to be a counterpart of U.S. Patent No. 5,442,008, which is cited on the attached listing.

EP 0 738 510: This document is believed to be a counterpart of U.S. Patent No. 5,733,558, which is cited on the attached listing.

EP 0 158 927: This document contains English language claims on pages 6-7. This document is also believed to be a counterpart of U.S. Patent Nos. 5,403,856, 5,684,016, 5,744,496, and 5,747,504, which are cited on the attached listing.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.


Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: February 7, 2006

By:   
Steven J. Scott  
Reg. No. 43,911

Complete if Known

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

6

Application Number

09/645,556

Filing Date

August 25, 2000

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1617

Examiner Name

Kim, Jennifer M.

Attorney Docket Number

02481.1702

## **U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS**

Examiner Initials	Cite No. <sup>1</sup>	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		3,983,140	28 Sept. 1976	Endo et al.	
		4,231,938	04 Nov. 1980	Monaghan et al.	
		4,346,227	24 Aug. 1982	Terahara et al.	
		4,444,784	24 April 1984	Hoffman et al.	
		4,448,784	15 May 1984	Glamkowski et al.	
		4,450,171	22 May 1984	Hoffman et al.	
		4,681,893	21 July 1987	Roth	
		4,722,810	02 Feb. 1988	Delaney et al.	
		4,739,073	19 April 1988	Kathawala	
		4,743,450	10 May 1988	Harris et al.	
		4,749,688	07 June 1988	Haslanger et al.	
		4,804,770	14 Feb. 1989	Karanewsky	
		4,857,520	15 Aug. 1989	Urbach et al.	
		5,223,516	29 June 1993	Delaney et al.	
		5,225,401	06 July 1993	Seymour	
		5,273,995	28 Dec. 1993	Roth	
		5,362,727	08 Nov. 1994	Robl	
		5,366,973	22 Nov. 1994	Flynn et al.	
		5,403,856	04 Apr. 1995	Henning et al.	
		5,430,145	04 July 1995	Flynn et al.	
		5,442,008	15 Aug 1995	Fulberth et al.	
		5,502,199	26 March 1996	Angerbauer et al.	
		5,504,080	02 April 1996	Karanewsky	
		5,525,723	11 June 1996	Robl	
		5,552,397	03 Sept. 1996	Karanewsky et al.	
		5,612,359	18 March 1997	Murugesan	
		5,679,671	21 Oct. 1997	Oinuma et al.	
		5,684,016	04 Nov. 1997	Henning et al.	
		5,733,558	31 Mar 1998	Breton et al.	
		5,744,496	28 Apr. 1998	Henning et al.	
		5,747,504	05 May 1998	Henning et al.	

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

Complete if Known

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

6

Application Number

09/645,556

Filing Date

August 25, 2000

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1617

Examiner Name

Kim, Jennifer M.

Attorney Docket Number

02481.1702

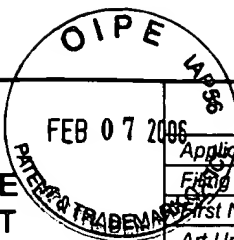
## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		EP 0 158 927 B1	23 Oct. 1985	Henning et al.		
		EP 0 363 934 B1	18 April 1990	Chen et al.		
		CA 2 026 686	01 May 1991	Tschollar		
		EP 0 481 522 B1	22 April 1992	Flynn et al.		
		EP 0 534 396 B1	31 March 1993	Warshawsky et al.		
		EP 0 534 492 B1	31 March 1993	Warshawsky et al.		
		EP 0 671 172 A1	13 Sept. 1995	Oinuma et al.		
		EP 0 738 510 A2	23 Oct. 1996	Breton et al.		
		EP 0 317 878 B1	31 May 1999	Fülberth et al.		
		CA 2 382 387	08 March 2001	Schoelkens et al.		
		CA 2 382 549	08 March 2001	Schoelkens et al.		

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		Schunkert H., et al., "Pharmacokinetics of ramipril in hypertensive patients with renal insufficiency," Eur J Clin Pharmacol., 37(3): 249-56 (1989)	
		Bauer B. et al., "An open multicenter study to assess the long-term efficacy, tolerance, and safety of the oral angiotensin converting enzyme inhibitor ramipril in patients with mild to moderate essential hypertension," J Cardiovasc Pharmacol., 13(Suppl 3): S70-4 (1989)	
		Kindler J., et al., "Therapeutic efficacy and tolerance of ramipril in hypertensive patients with renal failure," J Cardiovasc Pharmacol., 13(Suppl 3): S55-8 (1989)	
		Becker R.H. et al., "Loop diuretics combined with an ACE inhibitor for treatment of hypertension: a study with furosemide, piretanide, and ramipril in spontaneously hypertensive rats," J Cardiovasc Pharmacol., 13(Suppl 3): S 35-9 (1989)	
		Heber M.E. et al., "First dose response and 24-hour antihypertensive efficacy of the new once-daily angiotensin converting enzyme inhibitor, ramipril," Am J Cardiol., 62(4):239-45 (1988)	
		Zabludowski J. et al., "A multi-centre comparative study between ramipril and enalapril in patients with mild to moderate essential hypertension," Curr Med Res Opin., 11(2): 93-106 (1988)	
		Kaneko Y. et al., "Effect of ramipril, a new angiotensin converting enzyme inhibitor, on diurnal variations of blood pressure in essential hypertension," Am J Cardiol., 59(10): 86D-91D (1987)	
		Tochikubo O. et al., "Effect of ramipril on 24-hour variability of blood pressure and heart rate in essential hypertension," Am J Cardiol., 59(10): 83D-85D (1987)	
		de Leeuw P.W. et al., "Short- and long-term effects of ramipril in hypertension," Am J Cardiol., 59(10): 79D-82D (1987)	
		Becker R.A. et al., "Ramipril: review of pharmacology," Am. J Cardiol., 59(10): 3D-11D (1987)	
		Predel H.G. et al., "Combined treatment of severe essential hypertension with the new angiotensin converting enzyme inhibitor ramipril," Am J Cardiol., 59(10): 143D-148D (1987)	

BEST AVAILABLE COPY



Complete if Known

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

of

6

Application Number

09/645,556

Filing Date

August 25, 2000

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1617

Examiner Name

Kim, Jennifer M.

Attorney Docket Number

02481.1702

## **NON PATENT LITERATURE DOCUMENTS**

	Walter U. et al., "Dose-response relation of the angiotensin converting enzyme inhibitor ramipril in mild to moderate essential hypertension," Am J Cardiol., 59(10): 125D-132D (1987)	
	Fukiyama K. et al., "Efficacy and safety of ramipril (HOE 498) in the treatment of hypertension: dose finding study," Am J Cardiol., 59(10):121D-124D (1987)	
	Karlberg B.E. et al., "Efficacy, tolerance and hormonal effects of a new oral angiotensin converting enzyme inhibitor, ramipril (HOE 498), in mild to moderate primary hypertension," Am J Cardiol., 59(10): 104D-109D (1987)	
	Stumpe K.O. et al., "Effects of the new angiotensin-converting enzyme inhibitor, ramipril, in patients with essential hypertension," Klin Wochenschr, 64(12): 558-62 (1986)	
	Bohm R.O. et al., "Studies on the antihypertensive effect of single doses of the angiotensin converting enzyme inhibitor ramipril (HOE 498) in man," Eur J Clin Pharmacol.; 30(5): 541-7 (1986)	
	de Leeuw P.W. et al., "Preliminary experiences with HOE 498, a novel long-acting converting enzyme inhibitor, in hypertensive patients," J Cardiovasc Pharmacol., 7(6): 1161-5 (1985)	
	Mordchai Ravid et al., "Long-Term Stabilizing Effect of Angiotensin-Converting Enzyme Inhibition on Plasma Creatinine and on Proteinuria in Normotensive Type II Diabetic Patients", Annals of Internal Medicine, Vol. 118, No. 8, pp. 577-581 (1993)	
	Lacourciere Y. et al., "Captopril or conventional therapy in hypertensive type II diabetics," Hypertension, 21: 786-94 (1993)	
	Robert H. Noth et al., "Diabetic Nephropathy: Hemodynamic Basis and Implications for Disease Management", Annals of Internal Medicine, Vol. 110, No. 10, pp. 795-813 (1989)	
	Giancarlo Viberti, "Etiology and Prognostic Significance of Albuminuria in Diabetes", Diabetes Care, Vol. 11, No. 10, pp. 840-845 (1988)	
	Hans-Henrik Parving et al., "Prevalence and causes of albuminuria in non-insulin-dependent diabetic patients", Kidney International, Vol. 41, pp. 758-762 (1992)	
	William F. Keane et al., "Renal Protective Effects of Angiotensin-Converting Enzyme Inhibition", The American Journal of Cardiology, Vol. 65, pp. 491-531 (1990)	
	Susan Savage et al., "Progressive Renal Insufficiency: The Role of Angiotensin Converting Enzyme Inhibitors", Advances in Internal Medicine, Vol. 37, pp. 85-101 (1991)	
	Anthony F. Lever, "Angiotensin II, Angiotensin-Converting Enzyme Inhibitors and Blood Vessel Structure", The American Journal of Medicine, Vol. 92 (Suppl 4B), pp. 35 S-38 S (1992)	
	T.F. Lüscher, "Angiotensin, ACE inhibitors and endothelial control of vasomotor tone", Basic Res Cardiol., Vol. 88 (Suppl 1), pp. 15-24 (1993)	
	Richard Donnelly, "Angiotensin-Converting Enzyme Inhibitors and Insulin Sensitivity: Metabolic Effects in Hypertension, Diabetes and Heart Failure", Journal of Cardiovascular Pharmacology, Vol. 20 (Suppl. 11), pp. S38-S44 (1992)	
	John D. Rutherford et al., "Effects of Captopril on Ischemic Events After Myocardial Infarction: Results of the Survival And Ventricular Enlargement Trial", Circulation, Vol. 90, pp. 1731-1738 (1994)	
	Victor J. Dzau, "Cardiac Renin-Angiotensin System", The American Journal of Medicine, Vol. 84 (Suppl 3A), pp. 22-27 (1988)	
	Victor J. Dzau, "Angiotensin converting enzyme inhibitors and the cardiovascular system", Journal of Hypertension, Vol. 10 (Suppl 3), pp. S3-S10 (1992)	
	SOLVD Investigators, "Effect of enalapril on survival in patients with reduced left ventricular ejection fractions and congestive heart failure", The New England Journal of Medicine, Vol. 325, No. 5, pp. 293-302 (1991)	
	SOLVD Investigators, "Effect of enalapril on mortality and development of heart failure in asymptomatic patients with reduced left ventricular ejection fractions", The New England Journal of Medicine, Vol. 327, No. 10, pp. 685-691 (1992)	

Complete if Known

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

4

of

6

FEB 07 2001

Application Number

09/645,556

Filed Date

August 25, 2000

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1617

Examiner Name

Kim, Jennifer M.

Attorney Docket Number

02481.1702

## NON PATENT LITERATURE DOCUMENTS

	K. Fred Gey et al., "Inverse correlation between plasma vitamin E and mortality from ischemic heart disease in cross-cultural epidemiology", Am J Clin Nutr., Vol. 53 (Supp 1), pp. S326-S334 (1991)	
	Shrikant I. Bangdiwala et al., "Studies of Left Ventricular Dysfunction (SOLVD) Registry: Rationale, Design, Methods and Description of Baseline Characteristics", The American Journal of Cardiology, Vol. 70, No. 33, pp. 347-53 (1992)	
	Salim Yusuf et al., "Effect of Angiotensin-Converting Enzyme Inhibitors in Left Ventricular Dysfunction: Results of the Studies of Left Ventricular Dysfunction in the Context of Other Similar Trials", Journal of Cardiovascular Pharmacology, Vol. 22 (Suppl 9), pp. S28-S35 (1993)	
	Nancy J. Brown et al., "Angiotensin-Converting Enzyme Inhibitors", Cardiovascular Drugs, Vol. 97, No. 14, pp. 1411-1420 (1998)	
	Michael Marre et al., "Prevention of diabetic nephropathy with enalapril in normotensive diabetics with microalbuminuria", BMJ, Vol. 297, pp. 1092-1095 (1988)	
	Staffan Björck et al., "Renal protective effect of enalapril in diabetic nephropathy", BMJ, Vol. 304, pp. 339-343 (1992)	
	Allan M. Lefer et al., "Cardioprotective Effects of Enalapril in Acute Myocardial Ischemia", Pharmacology, Vol. 29, pp. 61-69 (1984)	
	Hans-Henrik Parving et al., "Effect of captopril on blood pressure and kidney function in normotensive insulin dependent diabetics with nephropathy", BMJ, Vol. 299, pp. 533-536 (1989)	
	E.R. Mathiesen et al., "Efficacy of captopril in postponing nephropathy in normotensive insulin dependent diabetic patients with microalbuminuria", BMJ, Vol. 303, No. 7, pp. 81-87 (1991)	
	Yoshio Taguma et al., "Effect of Captopril on Heavy Proteinuria in Azotemic Diabetics", The New England Journal of Medicine, Vol. 313, No. 26, pp. 1617-1620 (1985)	
	Marc A. Pfeffer et al., "Survival after an experimental myocardial infarction: beneficial effects of long-term therapy with captopril", Circulation, Vol. 72, No. 2, pp. 406-412 (1985)	
	Robert L. Hall et al., "Captopril Slows the Progression of Chronic Renal Disease in Partially Nephrectomized Rats", Toxicology and Applied Pharmacology, Vol. 80, pp. 517-526 (1985)	
	Staffan Björck et al., "Beneficial effects of angiotensin converting enzyme inhibition on renal function in patients with diabetic nephropathy", BMJ, Vol. 293, pp. 471-774 (1986)	
	Eva Hommel et al., "Effect of captopril on kidney function in insulin-dependent diabetic patients with nephropathy", BMJ, Vol. 293, pp. 467-470 (1986)	
	Hans-Henrik Parving et al., "Protection of kidney function and decrease in albuminuria by captopril in insulin dependent diabetics with nephropathy", BMJ, Vol. 297, pp. 1086-1091 (1988)	
	Jan E. Heeg et al., "Reduction of proteinuria by angiotensin converting enzyme inhibition," Kidney International, Vol. 32, pp. 78-83 (1987)	
	V. J. Dzau, "Clinical implications for therapy: possible cardioprotective effects of ACE inhibition," Br J Clin Pharmacol., Vol. 28, pp. 183S-187S (1989)	
	Michel Marre et al., "Converting enzyme inhibition and kidney function in normotensive diabetic patients with persistent microalbuminuria," BMJ, Vol. 294, pp. 1448-1452 (1987)	
	The CONSENSUS Trial Study Group, "Effects of Enalapril on Mortality in Severe Congestive Heart Failure," The New England Journal of Medicine, Vol. 316, No. 23, pp. 1429-1435 (1987)	
	Nancy J. Brown et al., "Selective Stimulation of Tissue-Type Plasminogen Activator (t-PA) <i>In Vivo</i> by Infusion of Bradykinin," Thrombosis and Haemostasis, Vol. 77, No. 3, pp. 522-525 (1997)	
	Tony Hayek et al., "Effect of Angiotensin Converting Enzyme Inhibitors on LDL Lipid Peroxidation and Atherosclerosis Progression in Apo E Deficient Mice," Circulation, Vol. 92, No. 8, p. 1-625 (1995)	
	Stefan Engeli et al., "Co-expression of renin-angiotensin system genes in human adipose tissue", Journal of Hypertension, Vol. 17, No. 4, pp. 555-560 (1999)	

Complete if Known

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

5

of

6

Application Number

09/645,556

Filing Date

August 25, 2000

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1617

Examiner Name

Kim, Jennifer M.

Attorney Docket Number

02481.1702

## NON PATENT LITERATURE DOCUMENTS

	Agnes Fogo et al., "Importance of angiogenic action of angiotensin II in the glomerular growth of maturing kidneys", Kidney International, Vol. 38, pp. 1068-1074 (1990)	
	Iekuni Ichikawa et al., "Glomerular Actions of Angiotensin II", The American Journal of Medicine, pp. 43-49 (1984)	
	Sharon Anderson et al., "Therapeutic Advantage of Converting Enzyme Inhibitors in Arresting Progressive Renal Disease Associated with Systemic Hypertension in the Rat", Hypertension and Glomerular Injury in Rats, Vol. 77, pp. 1993-2000 (1986)	
	Mordchai Ravid et al., "Long-Term Renoprotective Effect of Angiotensin-Converting Enzyme Inhibition in Non-Insulin-Dependent Diabetes Mellitus", Arch Intern Med., Vol. 156, pp. 286-289 (1996)	
	The Acute Infarction Ramipril Efficacy (AIRE) Study Investigators, "Effect of ramipril on mortality and morbidity of survivors of acute myocardial infarction with clinical evidence of heart failure", The LANCET, Vol. 342, pp. 821-828 (1993)	
	Paul M. Ridker et al., "Stimulation of Plasminogen Activator Inhibitor <i>In Vivo</i> by Infusion of Angiotensin II – Evidence of a Potential Interaction Between the Renin-Angiotensin System and Fibrinolytic Function", Circulation, Vol. 87, No. 6, pp. 1969-1973 (1993)	
	G.B. John Mancini et al., "Angiotensin-Converting Enzyme Inhibition with Quinapril Improves Endothelial Vasomotor Dysfunction in Patients with Coronary Artery Disease – the TREND (Trial on Reversing Endothelial Dysfunction) Study", Circulation, Vol. 94, No. 3, pp. 258-265 (1996)	
	Piero Ruggenenti et al., "Renal function and requirement for dialysis in chronic nephropathy patients on long-term ramipril: REIN follow-up trial", The LANCET, Vol. 352, pp. 1252-1256 (1998)	
	Rhonda Rowland, "Cardiology mapping new approaches to treatment," cnn.com, providing a date of November 1999	
	The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (1997)	
	Merck Index, 12 <sup>th</sup> Ed., pp. 1394-1395 (1996)	
	News Release, "Hope Study Indicates Ramipril Could Save One Million Lives Each Year", distributed by PR Newswire Europe Ltd. on behalf of McMaster University health Sciences, providing a date of May 1999	
	Wolfgang Linz et al., "Long-term ACE Inhibition Doubles Lifespan of Hypertensive Rats," Circulation, Vol. 96, No. 9, pp. 3164-3172 (1997)	
	Basis of Internal Medicine, 4 <sup>th</sup> Edition, Edited by Chen Haozhu, Peoples Medical Publishing House, pp. 226, 227, 230, 232, 238, 242, and 243 (1996), and partial translation	
	Leslie Papp, "Researchers call off \$11-million heart study," published in the Toronto Star newspaper, p. A5 (1999)	
	Susan Clairmont, "Heart Doc Loses Hope \$11M Research Project Ends Early," Hamilton Spectator newspaper, p. A3, providing a date of May 1999	
	Suzanne Morrison, "Heart Drug Called Major Discovery Ramipril Better Than Aspirin, Fewer Side Effects, Hamilton Spectator newspaper, p. A7, providing a date of May 1999	
	Leslie Papp, "Aborted vitamin E study will be given second look," Toronto Star newspaper, p. A5 (May 1999)	
	Susan Jeffrey, "New HOPE in heart study," Medical Post, vol. 35, No. 20, p. 1 (May 1999)	
	Karen Tu et al., "The striking effect of the Heart Outcomes Prevention Evaluation (HOPE) on ramipril prescribing in Ontario," Canadian Medical Association Journal, Vol. 168, No. 5, pp. 553-557 (2003)	
	Wilbert S. Aronow, "Treatment of Congestive Heart Failure in Older Persons," JAGS, Vol. 45, No. 10, pp. 1252-1258 (1997)	
	Salim Yusuf et al., "Changes in Hypertension Treatment and in Congestive Heart Failure Mortality in the United States," Hypertension, Vol. 13, No. 5, pp. 174-179 (1989)	
	Karl Swedberg et al., "Effects of the early administration of enalapril on mortality in patients with acute myocardial infarction," New England Journal of Medicine, Vol. 327, No. 10, pp. 678-684 (1992)	

Complete if Known

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

6

of

6

Application Number

09/645,556

Filing Date

August 25, 2000

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1617

Examiner Name

Kim, Jennifer M.

Attorney Docket Number

02481.1702

## NON PATENT LITERATURE DOCUMENTS

	Claude R. Benedict et al., "Comparative Neurohormonal Responses in Patients with Preserved and Impaired Left Ventricular Ejection Fraction: Results of the Studies of Left Ventricular Dysfunction (SOLVD) Registry," JACC, Vol. 22 (4 Supp A), pp. 146A-153A (1993)	
	Salim Yusuf, "Overview of the Design and Key Results of the Studies of Left Ventricular Dysfunction (SOLVD)," Heart Failure, Vol. 9, pp. 28-40 (1993)	
	F. X. Kleber, "Socioeconomic Aspects of ACE Inhibition in the Secondary Prevention in Cardiovascular Diseases," American Journal of Hypertension, Vol. 7, No. 9, pp. 112S-116S (1994)	
	Giancarlo Viberti et al., "Effect of Captopril on Progression to Clinical Proteinuria in Patients With Insulin-Dependent Diabetes Mellitus and Microalbuminuria," JAMA, Vol. 26, No. 4, pp. 275-279 (1994)	
	Carl Pepine, "Ongoing Clinical Trials of Angiotensin-Converting Enzyme Inhibitors for Treatment of Coronary Artery Disease in Patients with Preserved Left Ventricular Function," JACC, Vol. 27, No. 5, pp. 1048-1052 (1996)	
	Lars H. Lindholm et al., "The Swedish Trial in Old Patients with Hypertension-2 (STOP-Hypertension-2): A Progress Report," Blood Pressure, Vol. 5, pp. 300-304 (1996)	
	Mordchai Ravid et al., "Long-term Renoprotective Effect of Angiotensin-converting Enzyme Inhibition in Non-insulin-dependent Diabetes Mellitus," Archives of Internal Medicine, Vol. 156, No. 3, pp. 286-289 (1996)	
	Patrizio Tatti, et al., "Outcome Results of the Fosinopril Versus Amlodipine Cardiovascular Events Randomized Trial (FACET) in Patients with Hypertension and NIDDM, Diabetes Care, Vol. 21, No. 4, pp. 597-603 (1998)	
	Lionel H. Opie, "Principles of Combination Therapy for Hypertension: What We Learn from the HOT and Other Studies - A Personal Point of View," Cardiovascular Drugs and Therapy, Vol. 12, No. 5, pp. 425-429 (1998)	
	Raymond O. Estacio et al., "Antihypertensive Therapy in Type 2 Diabetes: Implications of the Appropriate Blood Pressure Control in Diabetes (ABCD) Trial," American Journal of Cardiology, Vol. 82, No. 9B, pp. 9R-14R (1998)	
	Marco Pahor et al., "New Evidence on the Prevention of Cardiovascular Events in Hypertensive Patients with Type 2 Diabetes," Journal of Cardiovascular Pharmacology, Vol. 32 (Supp 2), pp. S18-S23 (1998)	
	Claudio Borghi et al., "Evidence-Based Medicine and ACE Inhibition," Journal of Cardiovascular Pharmacology, Vol. 32 (Supp 2), pp. S24-S35 (1998)	
	Piero Ruggenenti et al., "Primary prevention of renal failure in diabetic patients: the Bergamo Nephrologic Diabetes Complication Trial," Journal of Hypertension, Vol. 16 (Supp 1), pp. S95-S97 (1998)	
	Nancy J. V. Bohannon, "Coronary artery disease and diabetes," Postgraduate Medicine, Vol. 105, No. 2, pp. 66-68, 71-72, and 77-80 (1999)	
	Lennart Hansson, "The Hypertension Optimal Treatment study and the importance of lowering blood pressure," Journal of Hypertension, Vol. 17 (Supp. 1), pp. S9-S13 (1999)	
	Guidelines Subcommittee, "1999 World Health Organization - International Society of Hypertension Guidelines for the Management of Hypertension," Journal of Hypertension, Vol. 17, No. 2, pp. 151-183 (1999)	
	Patent File History of Canadian Patent No. 2,382,387	
	Patent File History of Canadian Patent No. 2,382,549	
	Notice of Allowance dated October 31, 2005, in U.S. Patent Application No. 10/694,001	

Examiner  
SignatureDate  
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.